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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98 M-0136, 98 M-0217, 98 M-0138, 98 M-0327, 98 M-0328, 98 M-0219, 98 M-0137, 98M-0404, 98M–0200, 98M–0140, 98 M-0231 , 98 M–0187, 98 M-0139, 98M–0201 , 98 M-0403, 98M–0162, 97M-0084, 98 M-0329, 98M-0450, 98M–0451 , 98M–0251 , 98 M-0507, 98M–0618, 98M-0604,98M4)619, 96M-0678, 98M-0679, 98 M-071 5, 98 M-071 1, and 98 M-0725]

Medical Devices; List of Premarket Approval Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the World Wide Web (WWW) at http: //www.fda.gov/cdrh/pma page. html. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document, when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1998 (63 FR 457 1), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to

discontinue publication of individual PMA approvals and denials in the **Federal Register.** Revised §§ 8 14.44(d) and 8 14.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet (http://www.fda.gov), by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register,** and FDA believes that the Internet is accessible to more people than the **Federal Register.**

In accordance with section 5 15(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant: in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of all PMA applications for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through August 12, 1998. There were no denial actions during this period. The list is in order by PMA number and provides the manufacturer's name, the generic name or trade name, and the approval date.

TABLE 1.—LIST OF APPROVAL PMAS FROM APRIL 24, 1997, THROUGH AUGUST 12, 1998

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P940001198M-0136	Gensia, Inc.	Genesa (R) System	September 12, 1997
P940015198M-021 7	Biomatrix, Inc.	Synvisc (R) Hylan GF 20	August 8, 1997

TABLE 1.—LIST OF APPROVAL PMA'S FROM APRIL 24, 1997, THROUGH AUGUST 12, **1998—Continued**

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P940016198M41 38	B. Braun of America, Inc	Heparin-induced Extracorporeal Precipitation (H.E.L.P.) System	September 19, 1997
P940025198M-0327	Lobob Laboratories	Lobob FURW Drop	April 30, 1998
P940026/98M90328	Lobob Laboratories	Rigid Gas Permeable Contact Lens Solution and Labob C/D/S Cleaning Disinfecting Storage Solution	April 28, 1998
P950031/98M–0219	Lobob Laboratories	Lobob Cleaner	April 3, 1998
P960036/98M-O137	Mentor Corp.	Posterior Chamber Intraocular Lens	December 22, 1997
P960057/98M-0404	Gliatech, Inc.	Inhibitor, Peridural Fibrosis	May 27, 1998
P970002198M-0200	Alliance Medical Technologies, Inc.	Monostrut Cardiac Value Prosthesis	September 30, 1997
P970003198M4140	Cyberonics, Inc.	Neurocybernetic Prothesis System NE–LYJ Stimulator, Autonomic Nerve, Implanted for Epile	July 16, 1997
P970012/98M–0231	Medtronic, Inc	Medtronic, Kappa Pulse Generator	January 30, 1998
P970017/98M+I 187	Hologic, Inc.	Acoustic Bone Densitometer Sahara Clinical Bone Sonometer	March 12, 1998
P970021/98M–0139	Gynecare, Inc.	Thermal Balloon Endometrial Ablation Thermachoice Uterine Balloon Therapy (UBT) System OB–MNB–Device, Thermal Ablation, Endometrial	December 12, 1997
P970038/98M–0201	Hybritech, Inc	'andem Free PSA Assays	March 10, 1998
P970044J98M-0403	Dornier Medical Sys terns, Inc.	Transurethral Microwave Thermotherapy System, Dornier Urowave Thermotherapy System, GU–MEQ–System, Hyperthermia, RF/Microwave Benign Post	May 29, 1998
P970052/98M-0162	cardiovascular Dynamics, Inc.	'act, Arc, Lynx, and Guardian Balloon Coronary Dilatation Catheters Percutaneous Transluminal Coronary Angioplasty (PTCA) CV–LOX-Catheters, Transluminal Coronary Angioplasty, PE	February 20, 1998
P930016/SO03/97M-0084	'ISX, Inc.	Excimer Laser for Ophthalmic Use	April 24, 1997
P930034/S009/98M–0329	Summit Technology, Inc.	SVS APEX Plus Excimer Laser Workstation and Emphasis Disc OP–LZS–LASER, System, Excimer	March 11, 1998
P960013/98M~450	Pacesetter. inc.	Tendril DX Models 1388 T/K Endocardial, Steroid Eluting Screw-In Pacing Leads and Ventritex Assure AFS Models 7010 T/K Endocardial Steroid Eluting Screw In Pacing Leads	June 20, 1997
P960042198M-0451	Spectranetics Corp.	2 French Laser Sheath Kit	December 9, 1997

TABLE 1.—LIST OF APPROVAL PMA'S FROM APRIL 24, 1997, THROUGH AUGUST 12, 1998—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P950009/S002/98 M-0251	Neopath, Inc.	Autopap Primary Screening System	May 5, 1996
P960013/98M–0450	St. Jude Medical	Locator Steerable Stylet Model 4036	June 15, 1998
P9600421001 /98 M-0451	Spectranetics Corp.	12 French Outer Sheath	June 16, 1998
P970062/98M–0507	BMT, Inc.	Genestone 190 Lithotripter	June 24, 1998
P970058/98M-0618	R2 Technology, inc.	M 1000 Image Checker	June 26, 1998
P960011 /98 M-0604	Bio-Technology General Corp.	Biolon 1 % Sodium Hyaluronate Viscoelastic Surgical Aid Fluid	July 16, 1998
P960018/98M-061 9	Healthcare Products Plus, Inc.	The Needlyzer The Needle Destroyer Model ND 2	July 16, 1998
P950005/98M–0678	Cordis Webster. Inc.	Cordis Webster Diagnostic/Ablation Deflectable Tip Catheter	July 22, 1998
P980015/98M-0679	3iomedical Disposal, Inc.	Sharpx Needle Destruction Unit	August 6, 1998
P970040198M-0715	Lunar	Achilles & Ultrasonometer	June 26, 1998
P970051/98M-0711	Cochlear Corp.	Nucleus 24 Cochlear Implant System	June 25, 1998
P960034/98M–0725	Pharmacia & UpJohn	Cleon Heparin Surface Modified (ASM) Ultraviolet light	August 12, 1998

1 This means generic name.

Dated: 12-15-98

December 15, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

D.B. Burlington
Director
Center for Devices and Radiological Health

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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